ANNEX II

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K020020

DEC 3 0 2002

1. Submitter's Identifications:
   Well-Life Healthcare Inc.
   Room 6C01, No. 5, Sec. 5, Hsin Yi Rd.,
   Taipei, Taiwan, R.O.C.

   Contact:
   Ms. Grace Chang
   Sales Manager

   Date of Summary Preparation: October, 2001.

2. Name of the Device:
   Well-Life TENS (Transcutaneous Electrical Nerve Stimulation Device), Model Mini-TENS series, including WL-2401, WL-2402, WL-2403, and WL-2302.

3. Information of the 510(k) Cleared Device (Predicate Device):

4. Device Description:

   The Mini-TENS series, including WL-2401, WL-2402, WL-2403, and WL-2302 are transcutaneous electrical nerve stimulator used for pain relief by applying an electrical current to electrodes, which are attached on the patient's skin. The output and waveform is adjustable according to the situation of patient.

   Mini-TENS series, models WL-2401, WL-2402, WL-2403, and WL-2302, consist mainly of two parts: the stimulus generator, electrode. The stimulus generator generates the output current specified as the input of controller. The output port transmits the output current to the electrode, which is attached to the patient's skin so as to transmit this stimulus current to the patient for pain relief.

   The stimulation mode for Mini-TENS is burst mode with fixed pulse width, pulse rate, frequency, and fixed timer. Only amplitude is adjustable. This operation way is considered the simplification from the burst mode of comparison clear model, WL-2102A. Every model of Mini-TENS has its individual stimulation operation cycle.

   The Mini-TENS series (WL-2401, WL-2402, WL-2403, and WL-2302) are almost identical in function outlook and specification. The main differences between these four models are indicated in the following table.

Model	Outlook	Time for each operation cycle	Combination of wave form	Wave form information			
				Type	Pulse rate (Hz)	Pulse width (μs)	Time duration
Mini-TENS WL-2401	Type A	60 minutes	Single wave form (A)	A	30	250	3s/ON, 5s/OFF
Mini-TENS WL-2402	Type B	15 minutes	A/1min→ B/1min→ C/1min, repeat 5 times	A	30~60 auto-change	250	6s/ON, 1s/OFF
				B	30	150~250 auto change	6s/ON, 1s/OFF
				C	30~60 auto change	150~250 auto change	6s/ON, 1s/OFF
Mini-TENS WL-2403	Type C	30 minutes	Single wave form (A)	A	25	115	4s/ON, 1s/OFF
Mini-TENS WL-2302	Type C	15 minutes	A/2min→ B/2min→ C/2min→ B/2min→ D/2min→ B/2min→ C/3min	A	2	115	2s/ON, 1s/OFF
				B	30	115	2s/ON, 1s/OFF
				C	4	115	ON
				D	15	115	4s/ON, 1s/OFF

The WL-2402 is the most complicate in these three models, so the assessment results for the features of performance and safety of this model could cover that of the other three models.

While comparing with the original 510(k) clear device, WL-2102A. The main difference between burst mode operation of WL-2102A and Mini-TENS are indicated as the following table:

Comparison features	Clear model	New models			
	WL-2102A	WL-2401	WL-2402	WL-2403	WL-2302
Timer control	15/30/60 mins adjustable	60 mins fixed	15 mins fixed	30 mins fixed	15 mins fixed
Burst duration time	0.1s/ON, 0.4s/OFF	3s/ON, 5s/OFF	6s/ON, 1s/OFF	4s/ON, 1s/OFF	2s/ON, 1s/OFF or 4s/ON, 1s/OFF or always ON
Pulse rate (Hz)	100Hz fixed	30Hz fixed	30~60Hz auto change	25Hz fixed	2/4/15/30 Hz auto change
Pulse width (μs)	0~260μs adjustable	250μs fixed	150~250μs auto change	115μs fixed	115μs fixed
Amplitude (mA)	0~80mA adjustable	0~50mA adjustable	0~50mA adjustable	0~50mA adjustable	0~50mA adjustable
Combination for the type of wave form	Single (A)	Single (A)	3 wave forms combination: A(1m)→B(1m)→C(1m), 5 repeat	Single (A)	4 wave forms combination: A(2m)→B(2m)→C(2m)→B(2m)→D(2m)→B(2m)→C(3m)

5. Intended Use:

Mini-TENS series including WL-2401, WL-2402, WL-2403, and WL-2302, is a portable, battery-powered, transcutaneous electrical nerve stimulators (TENS device) that are used in the treatment of pain syndromes, that is intended for use on intact skin, and that do not require surgical intervention or violation of the skin surface.

The electrode is included in the packing of Mini-TENS series.

Because that all the performances tested are completely within the limit of standard, and all the labeling is provided according to the requirement of standard, the Well-TENS series fall completely within the scope of clause 1 of ANSI/AAMI NS4-1985.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

Features	*Clear model*	*New model*			
	WL-2102A	*WL-2401*	*WL-2402*	*WL-2403*	*WL-2302*
1. 510(k) Number	K002874	*K020020*	*K020020*	*K020020*	*K020020*
2. Device Name, Model	Well-TENS, WL-2102A	Mini-TENS, WL-2401	Mini-TENS, WL-2402	Mini-TENS, WL-2403	Mini-TENS, WL-2302
3. Manufacturer	Well-Life	Well-Life	Well-Life	Well-Life	Well-Life
4. Power Source(s) - Method of Line Current Isolation - Patient Leakage Current Normal condition Single fault condition	1x9V Alkaline Type BF < 0.001mA Not tested	1x3V Lithium Type BF < 0.001mA Not tested	1x3V Lithium Type BF < 0.001mA Not tested	1x3V Lithium Type BF < 0.001mA Not tested	1x3V Lithium Type BF < 0.001mA Not tested
5. Number of Output Modes	3 (B/C/M)	1 (Burst mode)	1 (Burst mode)	1 (Burst mode)	1 (Burst mode)
6. Number of Output Channels - Synchronous or Alternating? - Method of Channel Isolation	2 Synchronous Type BF	1 Synchronous Type BF	1 Synchronous Type BF	1 Synchronous Type BF	1 Synchronous Type BF
7. Regulated Current or Regulated Voltage?	RC	RC	RC	RC	RC
8. Software/Firmware/microprocessor Control?	Firmware	Firmware	Firmware	Firmware	Firmware
9. Automatic Overload Trip?	No	No	No	No	No
10. Automatic No-Load Trip?	No	No	No	No	No
11. Automatic Shut Off?	Yes	Yes	Yes	Yes	Yes
12. Patient Override Control?	No	No	No	No	No
13. Indicator Display: - On/Off Status? - Low Battery? - Voltage/Current Level?	 Yes No No	 Yes No No	 Yes No No	 Yes No No	 Yes No No
14. Timer Range	15/30/60 minutes adjustable	60 minutes	15 minutes	30 minutes	15 minutes

Features	*Clear model*	*New model*			
	WL-2102A	*WL-2401*	*WL-2402*	*WL-2403*	*WL-2302*
15. Compliance with Voluntary Standards?	ANSI/AAMI NS4	ANSI/AAMI NS4	ANSI/AAMI NS4	ANSI/AAMI NS4	ANSI/AAMI NS4
16. Compliance with 21 CFR 898? (*Becomes mandatory beginning May, 9, 2000)	Yes	No	No	No	No
17. Weight (g)	135	19	19	19	19
18. Dimensions (in) [W×H×D]	92×62×25	60×47.3×14.6	60×47.3×14.6	56×26×8	56×26×8
19. Housing Materials and Construction	Plastic	Plastic	Plastic	Plastic	Plastic

Table for the comparison of output specifications for mini TENS

Specification	*Clear model*	*New model*			
	WL-2102A	*WL-2401*	*WL-2402*	*WL-2403*	*WL-2302*
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (+/-20%) @ 500 Ω @ 2 kΩ @ 10 kΩ	 38V 55V 130V	 32V 42V 80.8V	 32V 42V 80.8V	 38.2V 52.8V 84.8V	 38.2V 52.8V 84.8V
Maximum Output Current (+/-20%) @ 500 Ω @ 2 kΩ @ 10 kΩ	 +76mA +55mA +13mA	 +64mA +42mA +8.08mA	 +64mA +42mA +8.08mA	 +76.2mA +52.8mA +8.48mA	 +76.2mA +52.8mA +8.48mA
Pulse Width (us)	30-260 adjustable	250	150~250 changeable	250	250
Frequency (Hz)	2-150 adjustable	30	30-60 changeable	25	2, 4, 15, 30 changeable
Beat Frequency (for interferential modes only)	NA	NA	NA	NA	NA
Symmetrical phases (for multiphasic waveform only)?	NA	NA	NA	NA	NA
Phase Duration (for multiphasic waveform only)	NA	NA	NA	NA	NA
Net Charge (μ C per pulse) @500Ω	20.8	16.0	16.0	8.76	8.76
Maximum phase Charge (μC)	22	12.5	12.5	9.2	9.2
Maximum Current Density (mA/cm^2)	0.18525	0.0333	0.0265	0.006	0.007
Maximum Power Density (W/cm^2)	0.0070395	0.0010656	0.000848	0.0002292	0.0002674

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

   Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement.

8. Conclusions

   The Mini-TENS series transcutaneous electrical nerve stimulator, WL-2401, WL-2402, and WL-2403, and WL-2302, have the same intended use and technological characteristics as the cleared device WL-2102A. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

   In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2002

Mr. Tony C. S. Chang
Wincent Consultant Co., Ltd.
No. 5, Alley 5, Lane Cheng Hsing,
Chung Ching Road, Pei Tun District,
Taichung, Taiwan, R.O.C.

Re: K020020
Trade/Device Name: Mini-TENS Series TENS Devices
Models WL-2401, WL-2402, WL-2403, WL-2302
Regulation Number: 21 CFR 882.5890
Regulation Name: TENS Device for Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: December 11, 2002
Received: December 12, 2002

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

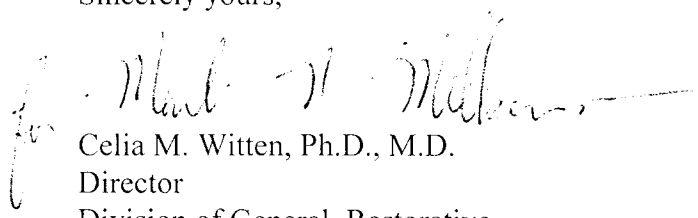
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ANNEX 1

510(k) Number (if known): k020020

Device Name: Mini-TENS / Model: WL-2401, WL-2402, WL-2403, WL-2302

Indications For Use:

The Mini-TENS including a series of TENS models (WL-2401, WL-2402, WL-2403, and WL-2302) is intended for symptomatic relief of chronic intractable pain.

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020020

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____

(Optional Format 1-2-96)